IBWA
INTERNATIONAL
BOTTLED WATER
ASSOCIATION

VIA Electronic Mail and by Hand

August 30, 2002

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Implementing Regulations of PL 107-188:
Section 305 (Registration) – Docket No. 02N-0276
Section 306 (Recordkeeping) – Docket No. 02N-0277

Dear Sir or Madam:

The International Bottled Water Association (IBWA)* appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (FDA) on the implementation of Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) (PL107-188), which President Bush signed into law on June 12, 2002.

IBWA is dedicated to helping ensure the safety and quality of bottled water. Bottled water producers utilize a multi-barrier approach, from source to finished product that helps ensure the safety and high quality of the product. IBWA is committed to preventing potential adverse events, both natural and man-made, through monitoring and testing, risk assessment, risk management, appropriate controls and procedures, and due diligence. Enhanced cooperation and the sharing of information between the bottled water industry and governmental agencies will help provide the appropriate evaluations and responses to potentially hazardous events.

I. Summary

IBWA supported the Act during the Congressional debate. The provisions of the Act will enhance the safety and security of the food distribution system in the United States. IBWA commends FDA on moving expeditiously in developing implementing regulations and offers whatever assistance the bottled water industry can provide in the timely promulgation of the regulations. It is imperative that the companies have clarity on what specific actions must be undertaken and what procedures must be initiated in order to be in compliance with the Act.

* IBWA is the trade association representing all segments of the bottled water industry. Our member companies produce and distribute about 80% of the bottled water sold and distributed in the United States. The association membership includes domestic and international bottlers and distributors

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It is particularly important that Sections 305 and 306 be clarified prior to December 12, 2003. IBWA's comments below highlight issues that will be need to addressed in the rule making by FDA. Specifically, IBWA urges the following:

1. **promulgation of final regulations and establishment of a electronic registration system at least 60 days prior to December 2003;**
2. **clarification of what is a "food facility" for purposes of registration and recordkeeping;**
3. **flexibility for companies to submit registrations and updates to FDA;**
4. **clear definition of what records must be maintained and flexibility of how they must be maintained;**
5. **limit the recordkeeping requirements to business-to-business transactions;**

II. Background

The bottled water industry has long been at the forefront of anticipating and responding to the need for safe, quality drinking water by consumers, above all in times of disasters or emergencies. Bottled water is fully regulated as a packaged food product by the U.S. Food and Drug Administration (FDA) and bound by FDA's quality, safety, inspection, enforcement and labeling requirements. Bottled water products are required to comply at all times with FDA Standards of Quality. As a packaged food, bottled water is subject to the full array of FDA enforcement actions including warning letters, recalls, civil (seizure and/or injunction) and criminal penalties under the Federal Food, Drug, and Cosmetic Act's misbranding and adulteration provisions, which help further ensure that only safe, high quality bottled water products reach the marketplace.

In addition to federal and state regulations, members of IBWA are required to adhere to standards in the IBWA Model Code that, in several cases, are stricter than FDA and state bottled water regulations. As a condition of IBWA membership, bottlers must submit to annual, unannounced plant inspections by an independent, third-party audit organization to verify compliance with the IBWA Model Code.

Bottled water producers utilize a multi-barrier approach, from source to finished product, which helps ensure the safety and high quality of the product. Many of the steps in a multi-barrier system are effective in safeguarding bottled water from microbiological and other contamination. Some of these measures include source protection and monitoring, distillation, reverse osmosis, filtration, ultraviolet light, and ozonation. Hazard Analysis and Critical Control Point (HACCP), which is required by the IBWA Model Code, also plays a key role in management of potential hazards. Bottlers are encouraged to "think outside the box" when considering potential hazards and preventive actions. Preparedness is the keystone of a HACCP program.

III. IBWA General Comments on Implementing Regulations

IBWA commends FDA on the attention and resources the Agency is devoting to promulgating regulations prior to the statutory implementation date and providing an electronic registration system for companies that manufacture, process, pack or hold food products.

IBWA urges FDA to promulgate final regulations and implement an electronic registration system no later than the first of October 2003. This will provide affected companies with the necessary notice and guidance to establish their internal policies and procedures for compliance with the tight timelines of the Act. This is particularly critical for IBWA members with international operations. Developing instructions for the identification and registration of the foreign food facilities that will be impacted by the Act will be a time consuming endeavor. As indicated in IBWA's comments, there is a particular need for clarifying regulations in Sections 305 (Registration of Food Facilities) and Section 306 (Maintenance and Inspection of Records for Foods).

A. Docket No. 02N-0276 - Section 305 (Registration of Food Facilities)

Overview

All food facilities, both domestic and foreign, are required to be registered with FDA before December 13, 2003, and FDA is required to issue an identification number to each facility. FDA must issue implementing regulations by December 12, 2003. However, if FDA does not promulgate final regulations, the owner, operator, or agent is still required to register the food facility with FDA. The Act specifies that the following information must be contained and updated in a food facility registration:

1. the name and address of the facility;
2. the name of the U.S. agent for the facility, if it is a foreign facility;
3. all trade names under which the registrant conducts business; and
4. the general food category, when determined necessary through guidance.

The Act limits the foreign food facility registration requirement to those facilities that manufacture, process, pack, or hold food products for export without further processing or packaging outside the United States. In addition, farms, restaurants, other retail food establishments, fishing vessels, and nonprofit food establishments in which food is prepared or served directly to the consumer are exempt from the registration provisions.

Section 305 encourages FDA to develop an electronic system as a registration option for companies. Facilities must be registered one time and the information must be updated in a timely manner.

IBWA Comments

Bottled water is fully regulated as a packaged food product by FDA and must adhere to FDA's standards of identity, safety, inspection, enforcement and labeling requirements. In addition, bottled water has its own unique set of bottled water Good Manufacturing Practice regulations (21 C.F.R. § 129.1 et seq.) while also being subject to the general Good Manufacturing Practice regulations. (21 C.F.R. § 110.3 et seq.) Thus, it is apparent that a bottling plant and the bottled water distribution centers will be required to register with FDA because they manufacture, process, pack, and/or hold bottled water, which is a regulated food product.

However, further clarification of which facilities will be required to be registered is needed for both domestic and foreign facilities. Facilities that manufacture food ingredients and additives (including processing aids and treatment compounds) which are incorporated into food products may be covered by the registration provisions, depending on the interpretation of FDA. As an example, the source waters for bottled water are typically obtained from springs, wells, or public water systems. The facilities for these types of water sources may be physically located within a bottling plant, detached but connected by pipes to a bottling plant, or not connected at all to the bottling plant, in which case the source water is hauled to the bottling plant from a water source. A spring house or pump house may have a building surrounding the water source and large storage silos for retaining the water until needed. The water is then hauled from the location to the bottling plant.

Rather than having municipal water systems and various other water sources register with the FDA, IBWA recommends clarification of this section so that it does not apply to such facilities as a pump house, spring house or municipal water system that provide source water to a bottling plant for bottled water. Because water becomes a regulated food product upon bottling, such facilities as a pump house, springhouse or municipal water system would not be required to register as a food facility.

For foreign facilities, clarification is needed on who is responsible for registering and what facilities must be registered. If foreign bottled water is sold to a distributor in a foreign country who then exports it to the United States without the knowledge of the foreign bottler, must the bottling plant be registered with FDA? If so, whose responsibility is it to register the facility? Likewise, is it the foreign bottler's responsibility to ensure that warehouses that temporarily store bottled water prior to loading for shipment are registered facilities? If all must be registered with FDA, it is critical that the final regulations so specify, and that there is enough advance notice to prevent a disruption in supply.

It is imperative that FDA have appropriate systems in place to administer the registration provisions by December 12, 2003. The identification number that must be

issued by FDA will be significant, especially as it relates to the marketplace. Retail and wholesale customers may insist on proof of registration prior to purchasing food products from a manufacturer or distributor. It is difficult to predict, at this juncture, how common this practice will become. However, if experience with other FDA-regulated products, such as pharmaceuticals, is indicative, major retail/distributor companies will require such proof. FDA's regulations should establish a maximum time limit, such as 30 days, for the Agency to issue a registration number.

IBWA urges the FDA to develop and implement an electronic registration system as quickly as possible. By permitting companies to register their facilities electronically, it will substantially reduce the amount of paperwork and increase the timeliness and usefulness of the registration information. Such a system could automatically assign a registration number to each facility and allow companies to update the required information easily. Otherwise, it will be the responsibility of the FDA to ensure the submitted corrections and updates are correctly entered into the registration system, a cumbersome undertaking for FDA given its other responsibilities under the Act.

FDA should specify that only changes in the required information need to be updated in a timely manner, and flexibility needs to be given to the interpretation of a "timely manner" to maximize the usefulness of the information. This is particularly true in updating "trade names" in the registration. The number of trade names, under which a corporation may be doing business from a particular facility, may change throughout a year. To encourage compliance with this requirement without an undue burden, flexibility in the submission and interpretation of this provision is necessary to incorporate these registration requirements into the other permitting and licensing functions of the individual companies.

In developing the registration system, FDA should allow companies the flexibility to submit registrations and updates for all the company facilities from corporate headquarters. Many small bottled water companies may not have access to an electronic registration system. FDA should consider allowing groups such as IBWA to register the bottling facilities on our members' behalf. Because each member must identify their bottling plants for purposes of third party inspections, IBWA has a unique data base of the bottling facilities throughout the United States and some foreign countries. Flexibility in the registration process is also needed because many larger companies have developed positions at their corporate headquarters that are responsible for the licensing and permitting required at the state and local levels. By providing the flexibility to manage the FDA registration process as appropriate for their company, the burdens on business will be diminished and compliance should increase. According to the legislative history of the Act (*Congressional Record*, December 20, 2001, page E 2387), the implementation of the registration must not unnecessarily disrupt the flow of commerce.

B. Docket No. 02N-0277 - Section 306 (Maintenance and Inspection of Records for Foods)

Overview

FDA may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. These records are needed by FDA for inspection to allow the Agency to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The regulations under this section shall take into account the size of a business.

IBWA Comments

The goal of this provision can be viewed as providing FDA with access to documented information that can be used to facilitate Agency investigation and response in the event an article of food presents "a credible threat of serious adverse health consequences or death to humans or animals." In this provision, IBWA recommends FDA apply the record maintenance requirements to business-to-business transactions. In implementing this provision, FDA should not take a prescriptive, or "one size fits all" regulatory approach.

It is important for FDA not to require a complete revamping of records for food products. As FDA is aware, many food products contain ingredients that are from multiple sources and are fungible. In the case of bottled water, bottlers may use multiple water sources in their bottling. The current drought conditions, in fact, demand flexibility from bottlers because of the need to obtain multiple water sources to meet demand while also meeting conservation restrictions. The bottlers' records will reflect their use of multiple water sources and when the water was delivered to the bottling plant.

IBWA urges FDA to specify who is required to keep records. In the case of bottled water ingredients, water sources should not be required to maintain records under this provision, since source water is not a food product. The purpose of the record provisions should be adequately served by looking at the bottling plant's records to see the sources of the water, thus narrowing the potential source of a health threat under investigation to a limited number of possibilities. Thus, the "traceability " and goal of the Act could be accomplished without unnecessarily burdening current business practices.

In addition, IBWA recommends that FDA provide flexibility in the storage of historical records and the access and production of such records. In some cases, companies will archive the records electronically on storage tapes and thus not have them "readily available." Others, because of space requirements, will store the physical records offsite. Given the range in sizes of bottled water producers, from family-owned small businesses to large corporate entities, such flexibility is vital. In order to facilitate an investigation, access to the information contained on the records seems to be the critical, time-sensitive need, rather than an examination of the physical record itself. A requirement to be able to provide information, rather than records, quickly to FDA in the case of imminent potential harm is more practical than establishing a record storage requirement that would specify how and where records must be maintained. Of course, the physical record will be produced after it has been retrieved by the company.

The records required to be kept as prescribed by the Act, are those related to the transfer of food products and packaging that enter a company and to whom they are delivered when they leave a company (immediate previous source and subsequent recipient of food). For example, IBWA presumes the intent is not to require separate record maintenance for a bottling plant and home and office delivery vehicles. In the case of packaging, IBWA recommends that the provisions apply to the final packaging, not the ingredients for the packaging, e.g., the water bottles and not the resins for the plastic to produce the bottles. IBWA recommends that FDA specify what information will be required to be maintained and urges the Agency to limit the information to the minimal amount of information necessary to trace the product either forward in the distribution chain or back to the sender.

In addition, IBWA requests flexibility in recordkeeping for containers. For example, a bottler may purchase 5-gallon bottles from supplier A and six months later purchase more 5-gallon bottles from supplier B to meet new customer demand and to replace worn bottles. Bottled water in these containers is delivered to homes and offices, but also to distributors and retailers for resale. The bottles are eventually returned to the bottler to be refilled and reused. After refilling and reuse, it would be an enormous undertaking to locate the record of delivery of a specific bottle and to determine the exact location of that bottle. The complexity of such a recordkeeping system would be extremely cost prohibitive. IBWA recommends that only the original purchase record be required to be maintained, and not follow the bottle through its life cycle of use.

The application of the record maintenance requirements should be limited to the business-to-business transactions. The look forward section should not apply to the person to whom the bottled water has been delivered for consumption. Unlike most food products, bottled water can be delivered directly to consumers' homes and offices. In many respects, it is very similar to retail grocery stores that deliver food products to

homes. In most cases, the delivery vehicle and personnel are part of the same company that bottles the water.

IV. Conclusion

IBWA looks forward to working with FDA in implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Again, we strongly urge FDA to expeditiously promulgate the regulations in order to allow sufficient time for companies to design and implement policy and procedures to comply with the provisions of the Act. Without the timely issuance of regulations, it will be very difficult to ensure the proper registration and procedures by food manufacturers and others affected by the Act's provisions. This is particularly true given the self executing construction of the Act.

If you need further information or have any questions, please do not hesitate to contact Patrick Donoho, IBWA Vice President of Government Relations at (703) 683-5213 ext. 108, or at pdonoho@bottledwater.org; or me at (703) 683- 5213 ext. 105, or at jdoss@bottledwater.org.

Sincerely,

Joseph Doss
President